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## The Significance of the Data Exclusivity and Its Impact on Generic Drugs

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### **The Significance of the Data Exclusivity Debate and its Impact on Generic Drugs**

*Srividhya Ragavan*

## THE SIGNIFICANCE OF THE DATA EXCLUSIVITY DEBATE AND ITS IMPACT ON GENERIC DRUGS

SRIVIDHYA RAGAVAN\*

*The following is a law review interview with Professor Srividhya Ragavan on the issues in interpretation of data exclusivity provisions under the TRIPS Agreement, and the impact of data exclusivity on generic drugs.*

### ***Q1. What is the role of Article 39 on trade secrets and data exclusivity?***

The historic origin of data exclusivity is from unfair competition principles. Essentially, Article 10bis of the Paris Convention for the Protection of Industrial Property,<sup>1</sup> which is a treaty administered by the World Intellectual Property Organization<sup>2</sup> requires member countries to provide for “effective protection against unfair competition.”<sup>3</sup> In essence, Article 10bis seeks to: a) establish “honest practices in industrial or commercial matters”<sup>4</sup> and to b) prevent actions such as dishonest manufacturing and other practices that mislead the public as to the nature and quality of the goods.

When the World Trade Organization (“WTO”)<sup>5</sup> was established, the TRIPS Agreement<sup>6</sup> incorporated the Paris Convention. Thus, the entire Part 7, including Article 39 of the TRIPS Agreement which elaborates protection of “undisclosed information” and “data submitted to governments or governmental agencies” as forming a part of the obligations of members to establish protection against unfair competition, was weaved into the

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<sup>1</sup> Paris Convention for the Protection of Industrial Property, Mar. 20, 1883, as last revised July 14, 1967, 21 U.S.T. 1583, 828 U.N.T.S. 305 at art. 10 [hereinafter “Paris Convention”].

<sup>2</sup> See Convention Establishing the World Intellectual Property Organization, July 14, 1967, 21 U.S.T. 1770, 1772–73, 828 U.N.T.S. 3, 11, 13 [hereinafter “WIPO Convention”]; see also *What Is WIPO?*, <http://www.wipo.int> (last visited June 18, 2011), See also World Intellectual Property Organization, *WIPO Treaties—General Information*, <http://www.wipo.int/treaties/en/general/>

<sup>3</sup> *Supra* note 1.

<sup>4</sup> *Supra* note 1, at art 10.

<sup>5</sup> Marrakesh Agreement Establishing the World Trade Organization, LEGAL INSTRUMENTS—RESULTS OF THE URUGUAY ROUND, vol. 1, 33 I.L.M 181 (1994), 1867 U.N.T.S. 14 [hereinafter “Marrakesh Agreement”]. See also *The WTO*, WORLD TRADE ORGANIZATION, available at [https://www.wto.org/english/thewto\\_e/thewto\\_e.htm](https://www.wto.org/english/thewto_e/thewto_e.htm).

<sup>6</sup> Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, vol. 31, 33 I.L.M. 1197 (1994), 1869 U.N.T.S. 299, reprinted in WORLD TRADE ORGANIZATION, THE RESULTS OF THE URUGUAY ROUND OF MULTILATERAL TRADE NEGOTIATIONS 365 (1995) [hereinafter “TRIPS Agreement”].

See also *Overview: the TRIPS Agreement*, WORLD TRADE ORGANIZATION, [https://www.wto.org/english/tratop\\_e/trips\\_e/intel2\\_e.htm](https://www.wto.org/english/tratop_e/trips_e/intel2_e.htm); see also Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, 19 U.S.C.A. § 4201.

TRIPS Agreement from the Paris Convention.<sup>7</sup> Of these, the protection for undisclosed information is essentially protection of trade secrets. In essence, it requires members to guarantee protection of any information that the owner deems a secret from unlawful disclosure and seeks to ensure honesty in commercial transaction.<sup>8</sup> Thus information such as customer lists, internal manuals, information about parts in factories, or such other information can qualify for protection as long as the owner of the information gains commercial value from it and keeps it a secret in the first place. It is important to appreciate that the TRIPS Agreement does not necessitate a trade secret statute (such as the state statutes in the United States which treat trade secret as a form of property).<sup>9</sup> It merely requires members to assure protection for undisclosed information which can be structured using the law of contract or other areas of the law. Breach of contract, breach of confidence and unlawful or fraudulent acquisition of undisclosed information by third parties can also form a part of the cause of action under this Article.

Data exclusivity relates to the second requirement in Article 39 of the TRIPS Agreement which is protection for data submitted to regulators, governments or governmental agencies.<sup>10</sup>

## ***Q2. What does Article 39.3 of the TRIPS Agreement say with regards to data exclusivity?***

Data exclusivity basically relates to the requirement of treating data (information) submitted to regulators, governments or governmental agencies as protected and thus, exclusive from third-party access. Typically, such data is submitted to regulators towards obtaining marketing clearances of application materials. For example, clinical trial information submitted to the federal agencies would be considered data submitted in support of the application to approve a compound as a drug. The submitted data is usually critical to prove the safety of the concerned drug. The details of such protection are outlined in paragraph 3 of Article 39 of the TRIPS Agreement and the protection relates solely to “the submission of undisclosed test or other data” as part of the approval process for marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities.<sup>11</sup>

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<sup>7</sup> *Id.* at art. 39.

<sup>8</sup> See TRIPS Agreement, *supra* note 6, at art. 39(1).

<sup>9</sup> See for e.g., UNIFORM TRADE SECRETS ACT, 14 U.L.A. 539 (1980) (amended in 1985); See also 18 U.S.C § 1839; see generally *Overview: The TRIPS Agreement*, WORLD TRADE ORGANIZATION, available at [https://www.wto.org/english/tratop\\_e/trips\\_e/intel2\\_e.htm](https://www.wto.org/english/tratop_e/trips_e/intel2_e.htm).

<sup>10</sup> *Supra* note 6, at art. 39.

<sup>11</sup> *Id.*

This protection is envisaged against unfair commercial use of “undisclosed test or other data” submitted to government regulators such as the U.S. Federal and Drug Administration (“FDA”) or equivalent agencies in other countries, provided it involves a “considerable effort” to generate the data.<sup>12</sup> The Article enunciates protection of the data to prevent disclosure and unfair commercial use of the information. There is one exception, however, in Article 39.3, and it applies where the disclosure of the data is deemed necessary to “protect the public.”<sup>13</sup>

For example, let us assume that Company A has a drug that is a subject of a patent application. During this time, the company conducts clinical trials over 300 patients and determines that the drug is safe to be used to treat say, acne. After the clinical trial is concluded, Company A submits the information for getting marketing approval of the drug. During this time, a competitor is able to oppose the patent application successfully such that the patent is either not granted, or is invalidated if already granted. Now, the information in the patent application will fall into public domain and can be used by generic drug companies rightfully for immediate marketing.

But the data exclusivity regime under Article 39.3 of the TRIPS Agreement will prevent generic drug companies from using the clinical trial data for a specific period of time, such as a period of 5 to 7 years of exclusivity in the United States depending on the type of drug. Thus even when the patent has failed, it results in Company A benefiting from an indirect market monopoly over the drug during the period of data exclusivity. The generic drug company is free to conduct its own clinical trials. But such duplication of clinical trial will result in duplicating the trial over patients unnecessarily and involves additional: a) cost to conduct the trial; b) delay in manufacturing the generic drug while trial is being conducted. Thus if generic drug companies duplicate a clinical trial that has already been conducted elsewhere, it will merely result in duplicative burdens in terms of time and cost. While the cost of the trial will be added to the cost of the drug and passed onto consumers, the delay from duplicating the clinical trial will result in delaying access to the consumers. Further, the use of the innovator’s clinical data by the generic drug company as part of its application for marketing approval before the end of the data exclusivity period will be considered unfair commercial use. That is, under Article 39.3, WTO Members mandating submission of clinical trial data are required to protect the use of submitted data by third parties as unfair commercial use; although Members can detail clear public interest exceptions allowing the use of the data for commercial purposes.

Data submitted for marketing of pharmaceutical or of agricultural chemical products is treated differently partly because of the powerful lobbies of pharmaceutical companies

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<sup>12</sup> *Id.*

<sup>13</sup> *Id.*

and interests they represent worldwide. This is an important issue for pharmaceutical companies because data exclusivity represents protection of important patient-related information on a drug or a compound. Protecting the information provides an economic opportunity by creating a new market on information relating to safety of the drug, helps preserve existing market for the compound, and, in some cases, provides market exclusivity for the compound for a little longer post the expiry of the patent. The issue here relates to access to medication and access to food which are critical for poorer nations. Hence it is important for developing countries to have a coherent approach.

By protecting the data and preventing its disclosure, the clinical trial data becomes exclusive information – that is, the information excludes access to other people. Under Article 39.3, Members of the WTO have an obligation to protect data against unfair commercial use. But members also have the flexibility to define the elements of “unfair commercial use.”<sup>14</sup> Most developing countries will allow use by government authorities to assess the efficacy and toxicity of a pharmaceutical product. Such allowance will be in public interest and will result in allowing the data to be used for getting the approval thereby facilitating the immediate marketing of the drug as soon as the data exclusivity period expires.

Importantly, given that access to medication has become a burden that the WTO, especially under the TRIPS Agreement, continues to bear poorly, such allowance will fall within the public interest exception of Article 39.3. Presumably, the definitions of public interest under the Doha Declaration on TRIPS Agreement and Public Health become applicable in this context as well, thereby enhancing the flexibility of Members to determine the constituents of the data exclusivity regime.<sup>15</sup>

### ***Q3. Is data submitted for marketing of pharmaceutical products and agricultural chemical products treated differently?***

The same assertions and logic that applies for pharmaceuticals applies for agricultural chemicals as well. In both of these cases, data exclusivity essentially provides an additional layer of protection. Both – innovator drug companies as well as agricultural companies – benefit from powerful lobby groups capable of asserting and negotiating benefits for their investors. In essence, what data exclusivity protects is the information relating to clinical trial and resulting data.

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<sup>14</sup> *Id.*; see also *WTO and the TRIPS Agreement*, WORLD TRADE ORGANIZATION, available at [http://www.who.int/medicines/areas/policy/wto\\_trips/en/](http://www.who.int/medicines/areas/policy/wto_trips/en/).

<sup>15</sup> See also World Trade Organization, Doha Declaration on TRIPS Agreement and Public Health, para. 6, Nov. 14, 2001, WTO Doc. WT/MIN(01)/DEC/1, 41 I.L.M. 746 (2002).

For example, if Drug A whose patent is owned by innovator drug company AMBA Inc., is effective against say, psoriasis, but results in arthritis pain in patients, clinical trial over Drug A will show a pattern. The data from the clinical trial will be essential for FDA to clear the drug for marketing after considering its safety. The data exclusivity regime in the U.S., for example, prevents regulatory bodies such as the FDA from examining the data to approve Drug A from any company other than AMBA Inc., during the exclusivity period. As discussed in the previous question, even if Drug A falls within the public domain, for whatever reason, during the term when data exclusivity prevails, a generic drug company cannot get the FDA to approve the competing product thus indirectly resulting in the innovator company having market exclusivity over a drug for the period of data exclusivity. The same applies to agricultural chemical products as well.

During the data exclusivity period, a regulator of chemical products such as the U.S. (FDA) will not use or apply information from the clinical trials of the first applicant to approve a generic version of the same drug.<sup>16</sup> The FDA grants new chemical entities (NCEs) a total data exclusivity period of up to 5 years.<sup>17</sup> However, in the case of pharmaceuticals, even if a generic drug company is able to successfully challenge the applicant's patent, the FDA will process the generic company's application for drug approval after the 4<sup>th</sup> year of the data exclusivity period, but not before.<sup>18</sup>

#### ***Q4. How does data exclusivity operate in practice for drug companies?***

Historically, data exclusivity represents a compromise between innovator drug companies and generic drug companies, whereby innovator companies get a period of exclusivity but once that exclusive period is over, a generic company can use the data for its own drug approval.<sup>19</sup> The compromise, first memorialized in the United States under the Hatch-Waxman Act, 1984 provides a period of exclusivity of 5 years to protect the original data of the clinical trials.<sup>20</sup> The Hatch-Waxman Act essentially allows for generic competition of off-patent products that are not protected by patents. In turn, it provides some risk-protection for the data that the innovator collects towards submission for

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<sup>16</sup> See Federal Food, Drug, and Cosmetic Act, 1938, 505(c)(3)(E), 505(j)(5)(F); 21 USC § 355; See also Small Business Assistance: Frequently Asked Questions for New Drug Product Exclusivity, U.S. FOOD AND DRUG ADMINISTRATION, available at <https://www.fda.gov/Drugs/DevelopmentApprovalProcess/SmallBusinessAssistance/ucm069962.htm>.

<sup>17</sup> See 21 USC 355 (b)(1) and (b)(2) under which applications for a new chemical entity can receive 5 years of exclusivity. See also *Frequently Asked Questions on Patents and Exclusivity*, U.S. FOOD AND DRUG ADMINISTRATION, available at <https://www.fda.gov/Drugs/DevelopmentApprovalProcess/ucm079031.htm#howlongexclusivity>.

<sup>18</sup> *Id.*

<sup>19</sup> See generally *Novo Nordisk A/S, et al. v Caraco Pharmaceutical Laboratories, Ltd., et al.*, 719 F.3d 1346 (Cir. June 18, 2013).

<sup>20</sup> See Drug Price Competition and Patent Term Restoration Act of 1984, 35 U.S.C. § 156 (1984) [hereinafter Hatch-Waxman Act]. See also, 21 C.F.R. 314.108.

regulatory approval. The enactment represents a compromise between two lobby groups – innovator pharmaceutical companies and the generic drug industry. Data exclusivity and the lack of a stock-piling exception are all by-products of such a compromise that is unique to, and typical of, American lobby politics. The important aspect to remember is that such compromises need not be emulated in every market, especially in a developing country market such as India.

As mentioned earlier, data exclusivity protects clinical trial data submitted to regulatory bodies as proof of safety. The exclusivity is a reward considering the risk that innovator companies take in terms of the cost of conducting the clinical trial and in subjecting patients to drugs that may be unsafe or even harmful.<sup>21</sup> In effect, the data exclusivity period allows drug companies to recoup the investment on clinical trials, which can run up to four separate phases involving several patients, their confidential information, treatment regimes and information on side effects and safety regimes of the medication.

Needless to specify, just like patents, data exclusivity represents another important tool for innovator companies to preserve market exclusivity which helps keep the price of the product high. Meanwhile, the access to medication debate has gained much support globally on account of three reasons:

- a) patent systems of countries such as the United States is emulated across the globe but is now being subject to world-wide criticism for facilitating more private property at the cost of public health in the case of pharmaceutical patents;
- b) escalating cost of the medications which has become an issue even in developed nations; and,
- c) important international reports, such as the UN High Level Panel Report on Access to Medication,<sup>22</sup> have underlined the need for access to medication in poorer nations.

The current perception of patents as access barriers and the resulting unpopularity on account of predatory pricing of pharmaceuticals (e.g., Bayer's Nexavar in India) has caused innovator pharmaceutical companies to find new tools to preserve market exclusivity. Increasing drug prices have become unpopular, and data exclusivity as an alternative is becoming a potent tool to retain market exclusivity indirectly. That is

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<sup>21</sup> *Patents and Exclusivity*, U.S. Food and Drug Administration, <https://www.fda.gov/downloads/drugs/developmentapprovalprocess/smallbusinessassistance/ucm447307.pdf>.

<sup>22</sup> See United Nations Secretary-General's High-Level Panel on Access to Medicines, UNITED NATIONS, available at <http://www.unsgaccessmeds.org/>.



partly why pharmaceutical lobby groups vigorously focused on increased data exclusivity protection under the now-doomed Trans-Pacific Partnership.<sup>23</sup>

#### ***Q5. What is the current Indian position on data exclusivity?***

The Indian Drugs and Cosmetics Act, 1940, under section 122E, provides for data exclusivity for a “new drug” for a total period of 4 years from the date of approval.<sup>24</sup> A “new drug” is not defined as a patented drug but simply a drug which has not been used in the country to any significant extent.<sup>25</sup> A new drug is a product that has not been recognized or licensed in India, or a drug recently licensed and approved for marketing, or a combination of drugs individually approved earlier but marketed as a combination, or vaccines and Recombinant DNA (r-DNA) derived drugs. Like the United States, the Indian law requires an applicant for a new drug to engage in extensive testing and clinical trials. But this requirement may be waived for purposes of “public interest” or if the new drug has been approved and marketed for several years in other countries.<sup>26</sup> Such a requirement is a standard norm to avoid duplication of trials in different jurisdictions which can result in increasing the cost and delaying the introduction of the drug in the market.

In the United States, the FDA approval of a drug for marketing is linked with patent protection. That is, when a generic drug company makes an application (ANDA application), the FDA will process the application only if there is no valid patent on the same. The tying-in of patent information with data exclusivity is called patent linkage.<sup>27</sup> Patent linkage results in delaying the entry of generic competition into the market. When the Hatch-Waxman Act was enacted, innovator pharmaceutical companies realized that they could not deny generic drugs market access anymore. Hence patent linkage was proposed as an alternative to delay the entry of generic competition.

The question is not whether patent linkage is beneficial or not. Countries that house innovator pharmaceutical companies would institute patent linkage because it is in their best interests. Countries such as India, which predominantly house a generic drug

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<sup>23</sup> See generally *What does the TPP say about Data Exclusivity and Biosimilars?*, MANAGED CARE, <https://www.managedcaremag.com/focus/what-does-tpp-say-about-data-exclusivity-and-biosimilars>.

<sup>24</sup> See DRUGS AND COSMETICS ACT, 1940, No.23 of 1940, INDIA CODE (1993), section 122E (amended 1995) (India), available at <http://cdsco.nic.in>.

<sup>25</sup> *Id.*

<sup>26</sup> *Id.*

<sup>27</sup> See G. Lee Skillington & Eric M. Solovy, *The Protection of Test and Other Data Required by Article 39.3 of the TRIPS Agreement*, 24:1 NORTHWEST JRNL OF INT. LAW 34(2003); See Ravikant Bhardwaj, K D Raju & M Padmavati, *The Impact of Patent Linkage on Marketing of Generic Drugs*, 18 J. OF INTELL. PROP. RTS. 316 (2013), available at [http://nopr.niscair.res.in/bitstream/123456789/20282/1/JIPR%2018\(4\)%20316-322.pdf](http://nopr.niscair.res.in/bitstream/123456789/20282/1/JIPR%2018(4)%20316-322.pdf).

industry, and other countries such as Brazil and Chile, which provide Universal Health Coverage, would be disadvantaged by patent linkage because it largely serves to delay generic drug companies from entering into the market. In effect, the generic drug company cannot get marketing approval and be ready for manufacturing its product until the patent expires. From the time the patent expires and until the generic drug is cleared for the market, the innovator will indirectly enjoy a market monopoly despite the expiry of the patent.

In India, marketing approval of the drugs is not linked with the status of patents. The Drug Controller primarily examines whether the drug has been tested for safety elsewhere and whether the data submitted to prove safety in another jurisdiction will be adequate for the drug to be introduced in India. The Indian position is that linking patent data with drug approval increases the burden of the generic drug company to prove the existence or otherwise of patents, and adds another layer of responsibility over the administrator in requiring them to verify patent data of application materials.

The question of patent linkage arose in India in relation to the approval of a generic version of 'sorafenib tosylate' used to treat renal cell cancer.<sup>28</sup> Bayer, the patent owner, approached the Supreme Court of India to prevent the grant of marketing approval to Cipla.<sup>29</sup> Bayer asserted that the TRIPS Agreement necessitated the establishment of patent linkage to prevent the Drug Controller from approving the marketing of drugs whose patent was not owned by the applicant, Cipla. The Delhi High Court was persuaded by the presence of a Bolar Provision under Section 107A of the Indian Patents Act, 1970 which specifically exempted the use of data for regulatory approval from infringement with a view to permit immediate availability of generic drugs in the market when the patent expires.<sup>30</sup> The Supreme Court sustained the judgment of the Delhi High Court and rejected the applicability of patent linkage in India. Nevertheless, the United States has repeatedly sought to pressurize India under the Special 301 process to recognize patent linkage on the grounds that Article 39 of TRIPS requires it.<sup>31</sup>

#### **Q6. Can you explain the debate on data exclusivity under the TRIPS Agreement?**

Article 39.3 of the TRIPS Agreement requires members to protect data submitted to regulators "against unfair commercial use."<sup>32</sup> The Article further requires Members to

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<sup>28</sup> Bayer Corp. v. Union of India, WP(C) No.7833/2008, (2008) (India), available at <http://lobis.nic.in/>.

<sup>29</sup> *Id.*

<sup>30</sup> *Id.*

<sup>31</sup> Sean M. Flynn, *Special 301 of the Trade Act of 1974 and Global Access to Medicine*, Journal of Generic Medicines, American University, WCL Research Paper No. 2010-25, available at [http://digitalcommons.wcl.american.edu/cgi/viewcontent.cgi?article=1000&context=pjip\\_facsch](http://digitalcommons.wcl.american.edu/cgi/viewcontent.cgi?article=1000&context=pjip_facsch).

<sup>32</sup> See TRIPS Agreement *supra* note 6, at Art. 39(3).

protect such data “against disclosure.” There is nothing in the TRIPS Agreement which suggests that disclosing the data to a government regulator must be construed as “unfair commercial use.” Such an interpretation would go against the construction of the objectives of the TRIPS Agreement under Article 7 and 8.<sup>33</sup> The commercial use of an approved pharmaceutical does not begin until the term of the patents that cover the application material expires. Indeed, if a patented drug is not approved and ready for the market at the time of the expiry of the patent term, the consumer is unfairly denied access to material that has fallen into the public domain. Also, the patent owner would benefit from an unfair commercial advantage on account of the market exclusivity after the expiry of the patent term to the detriment of consumers.

The TRIPS Agreement clearly does not advocate data exclusivity or patent linkage in a manner that the developed nations, particularly the United States, seek. Developed countries assert that data exclusivity is a requirement under the TRIPS Agreement. They also claim that the TRIPS Agreement prevents regulatory authorities from considering the status of patents before approving a generic substitute. Thus developed countries believe that having a specific period during which drug regulators are prevented from relying on test data submitted to approve generic substitutes is the way to keep data exclusive.

Before the TRIPS Agreement was negotiated, most countries allowed reliance on originator test data to approve generic products.<sup>34</sup> Generic manufacturers only had to prove bioequivalence, which is that their product was chemically identical to the brand-name, original product. This approach was consumer-friendly in that it enabled introduction of generics into the market as soon as the patent expired. The importance of preserving this traditional approach is underscored by the recent UN High Level Panel Report on Access to Medicines,<sup>35</sup> the WIPO Development Agenda<sup>36</sup> and the WHO Studies,<sup>37</sup> all of which highlight the importance of access to medicines.

Data exclusivity and patent linkage also affect the operation of compulsory licenses. Basically, when there is a public health crisis, the presence of patent linkage and data exclusivity should not operate to prevent a regulator from approving drugs that may be

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<sup>33</sup> See TRIPS Agreement *supra* note 6, at Art. 7, 8.

<sup>34</sup> *Supra* note 5.

<sup>35</sup> See Report of the United Nations High Level Panel Report on Access to Medicines, UNITED NATIONS, (Sep. 14, 2016), available at <http://www.unsgaccessmeds.org/final-report/>.

<sup>36</sup> See generally Development Agenda for WIPO, WORLD INTELLECTUAL PROPERTY ORGANIZATION, available at <http://www.wipo.int/ip-development/en/agenda/>

<sup>37</sup> Ed Silverman, Hepatitis C drugs remain unaffordable in many countries, says WHO study, PHARMALOT, (May 31, 2016) available at <https://www.statnews.com/pharmalot/2016/05/31/gilead-hepatitis-drug-prices-who/>.

See also Over 1 million treated with highly effective hepatitis C medicines, WORLD HEALTH ORGANIZATION, (27 October 2016), available at <http://www.who.int/mediacentre/news/releases/2016/hepatitis-c-medicines/en/>.

needed to resolve the crisis. Article 39.3 of the TRIPS Agreement is certainly not worded to impose restrictions such that data exclusivity becomes a hurdle to public health. However, even assuming that it was the case, such a reading of Article 39.3 would not survive the Doha Declaration on Public Health.<sup>38</sup>

***Q7. Does India need a better data exclusivity provision? If yes, what should such a provision contain?***

No, India has a perfectly fine data exclusivity provision.

***Q8. The most common argument in favour of data exclusivity is that collecting test data requires time and financial investment; therefore the entity gathering this data should be entitled to a period of exclusivity. As you note in an article, "The cost of undertaking tests is considerable, involves human subjects and is, therefore, an arduous exercise." How should this concern be addressed?***

The patent regime vests a monopoly with the innovator drug company for a term of 20 years during which time companies have a history of levying a cost price to cover over 200% to 300% of their investments. Recent cases such as Mylan's pricing of Epipen and Pfizer's profits from Lipitor are great examples of the windfall that results when a drug is patented.<sup>39</sup> In order to get such a huge margin of profits, research and development along with the associated activities are risks that every innovator undertakes, and, when successful, is rewarded with a patent along with the resulting profits from the monopoly. The cost of clinical trials is a part of the process of getting the patented product into the market and is a risk that innovator drug companies need to undertake. There is no need to add another layer of profit protection for conducting clinical trials.<sup>40</sup>

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<sup>38</sup> World Trade Organization, Ministerial Declaration of November 14, 2001, ¶ 17, WT/MIN(01)/DEC/1, 41 I.L.M. 746 (2002); see also *The Doha Declaration Explained*, available at [https://www.wto.org/english/tratop\\_e/dda\\_e/dohaexplained\\_e.htm](https://www.wto.org/english/tratop_e/dda_e/dohaexplained_e.htm).

<sup>39</sup> Dan Mangan, *Mylan CEO Bresch said Company has learned from Epipen Furor*, CNBC (Jan. 10, 2017), available at <http://www.cnbc.com/2017/01/10/mylan-ceo-bresch-said-company-has-learned-from-epipen-furor-hopes-trump-appreciates-decisive-action-on-pricing-controversy.html>; see also Todd Campbell, *Pfizer Gets Back to Growth*, THE MOTLEY FOOL (Feb. 9, 2016), available at <https://www.fool.com/investing/general/2016/02/09/pfizer-gets-back-to-growth.aspx>.

<sup>40</sup> Srividhya Ragavan & Moushami Joshi, *Backdoor Patents could Hurt Patients*, HINDU BUSINESS LINE (Dec. 27, 2016), available at <http://www.thehindubusinessline.com/opinion/extending-data-exclusivity-for-a-drug-after-clinical-trials-is-not-a-good-idea/article9446406.ece>.

***Q9. While it might be true that data exclusivity negatively impacts generic drugs, are generics really a long-term solution to the global healthcare crisis and the problem of access to medicines?***

There are three reasons why generics have become a part of the global pharmaceutical industry. First, generics are a necessary part of the food-chain of global pharmaceuticals. They are required to not just cater to the health needs of the poorer countries but also to kick-start innovation in these nations.

Second, historically, copying has been the first step for innovation even in the developed world. Thus for innovation in pharmaceuticals to proliferate all over the world, generics will serve as the first step to kick-start the industry. Especially for least-developed countries, the leap to innovation in pharmaceuticals in the future will occur only when they take the first step of being able to establish generic drug manufacturing facilities locally.

Third, even in developed nations that are obsessed with patents, like the United States, the astronomical cost of medication has resulted in an increased appreciation for the role of generics. Thus generics are viewed as important components to enable market competition as well as to challenge bad patents. In all, the generic drug industry represents an important industry catering to the healthcare needs of a large segment of the global population.